

**K143560 CygneX I System**Oct 5, 2015  
293 days to decisionK143560 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k143560/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 16, 2014
Decision date	Oct 5, 2015
Days to decision	293 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Accuthera, Inc.</b>
Location	Kawasaki, JP
Contact	Eiji Tanabe
510(k) history	1 submissions · 1 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143560/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026